

REMARKS

Claims 1-15 and 38-51 are pending in this application. Claims 3-5, 15 and 38 40 are withdrawn from consideration as being drawn to a non-elected invention. By the present amendment claims 1, 2, 7, 8, 12, 14 and 41 are amended. Claims 11, 48 and 49 are hereby canceled without prejudice or disclaimer, and new claims 52-57 are hereby added.

Support for the amendments to the claims is found in the last paragraph of page 4, the first full paragraph of page 6, paragraphs 2-5 of page 7, and paragraphs 2 and 3 of page 8. Support for new claims 52 and 54 is found on page 8, last paragraph. Support for new claims 53 and 55 is found in the first full paragraph of page 6. Support for new claims 56 and 57 is found in the last paragraph on page 4. The amendments and new claims add no new matter. Applicants respectfully request entry of the present amendment.

In view of the above-described amendments, reconsideration of claims 1, 2, 6-10, 12-14, 41-47, 50, and 51 and consideration of new claims 52-57 are respectfully requested.

Objections

The disclosure is objected to for containing a hyperlink. As requested by the Patent Office, applicants have amended the first full paragraph of the Background to remove reference to the hyperlink.

§ 102 Rejections

Claims 1, 2, 6-14, 41, 43, 45, 47-51 are rejected under 35 USC § 102 (b) as being anticipated by Giese (USPN 4,478,914) (hereinafter "Giese").

Claims 11, 48, and 49 have been canceled rendering the rejection of these claims moot.

Independent Claims 1, 8, 12 and 41 have been amended to recite that the multimeric biopolymer comprises a plurality of monomeric units selected from the group consisting of proteins, polypeptides, nucleic acids or peptide nucleic acids that are covalently bonded to each other. Giese recites that the initial component (i.e., the vitamin biotin) in his multilayer structure may be covalently bonded to a surface (See, column 5, lines of Giese.) Giese, however, does not mention covalently bonding the protein components (e.g. avidin molecules) of his multilayer structure to each other. As explained in the attached Rule 1.132 Declaration of Dr. Leonidas

Bachas, the avidin molecules in Giese are indirectly linked to each other by non-covalent bonds between avidin and the intervening molecules of a ligand (biotin or biotin-extender). (See paragraph 3 of the attached 1.132 Declaration) Since biotin is a ligand for avidin, it is expected that the protein (avidin) and the vitamin (biotin) molecules are linked to one another by ionic interactions, hydrophobic interactions, hydrogen bonds, van der Waals forces or a combination of these non-covalent linkages.(Id.) As described in column 2, lines 35-40 of Giese, such structure is formed by "repetition of the following sequence of steps (a-d) to build up successive layers of avidin and extender: (a) add avidin; (b) wash away unbound avidin (c) add extender; (d) wash away unbound extender.(See column 2, lines 35-40 of Giese).

Lacking a multimeric structure comprising a plurality of protein, or polypeptides, or both that are covalently bonded to each other, Giese does not anticipate independent claims 1, 8, 12, and 41 of the present application. Claims 2, 7, 9, 10, 43, and 50 depend from claim 1 and, for the same reason, are not anticipated by Giese. Claims 13, 14, and 45 depend from claim 12 and, for the same reasons, are not anticipated by Giese. Claims 47 and 51 depend from claim 41 and, for the same reasons, are not anticipated by Giese.

§ 103 Rejections

Claims 42, 44, and 46 are rejected under 35 USC § 103 (a) as being unpatentable over Giese in view of Houghten (USPN) 4,886,663. The Patent Office stated:

Houghten teaches a synthetic multimeric polypeptides pf (sic) a heat-stable endotoxin of E. coli, wherein Houghten teaches that the multimeric form comprises linking of monomeric units of polypeptides with peptide bonds.... Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the multimeric polypeptides (sic) comprising peptide bonds as taught by Houghten to achieve expected advantage of developing a multimeric biopolymer (sic) resembling a natural polypeptide because Houghten suggest that "biological activity and antigenicity can be obtained by using synthetic polypeptides containing at least one intramolecular, intrapolypeptide cystine disulfide bond. An ordinary practitioner would have been motivated to combine the multimeric biopolymer of Giese with multimeric polypeptides comprising peptide bonds as taught by Houghten to improve the synthetic multimeric biopolymer structure by linking the monomeric units (sic) with peptide bonds for the expected advantage of developing a multimeric polypeptide to mimic the natural polypeptide with correct orientation and folding to contain desired partial biological activity. (emphasis added)

Giese recites a process for altering the surface properties of a substrate (See column 1, lines 50-58, column 3, lines 36-38, column 4, lines 50-56 of Giese). The process involves stepwise attachment of “repetitive specific, molecular or particulate layers of a proteinaceous material and ligand material [to the surface]. (See column 1, lines 52-55 of Giese.) The process is simple allows one to readily change the adsorptive, toxicity, and charge properties of the underlying surface.

Houghten recites a 14 amino acid polypeptide that can be used in a diagnostic or as an immunogen or vaccine to protect against diarrheal infections. (See column 5, lines 37-42 of Houghten.) The immunogen can be a monomer or a multimer that comprises the 14 mer covalently linked to a carrier protein or multiple units of the 14 mer. The 14 mers in the multimeric immunogen of Houghten are linked to each other by peptide bonds. The 14 mers in the multimeric structure of Houghten do not comprise a binding region for a ligand selected from the group consisting of a sugar, a peptide, a nucleic acid, a hormone, a vitamin, a co-factor, an anion other than a hydroxyl ion and a cation other than a hydrogen ion. (See paragraph 4 of the attached 1.132 Declaration of Dr. Leonidas Bachas.) Thus, the multimeric polypeptide of Houghten lacks some of the features of the multimeric protein recited in claims 42, 44, and 46 of the instant application.

There is nothing in Giese to suggest that the multilayer structure disclosed in Giese should be modified by combining the ligand-protein structure that is taught therein with a totally different multimeric polypeptide having peptide bonds or alternatively by replacing the ligand protein structure taught therein with a multimeric protein that comprises peptide bonds. There is nothing in Giese to suggest that such modifications would improve the ability of the Giese multilayer structure to change the surface properties of an underlying substrate. There is nothing in Giese to suggest that the multilayer structure that is taught therein has biological properties that can be improved by combining a totally unrelated multimeric polypeptide having peptide bonds with his multilayer structure or by replacing his ligand-protein multilayer with a multimeric polypeptide having peptide bonds. There is nothing in Giese to suggest that it would be desirable to add a multimeric polypeptide having peptide bonds to his multilayer ligand protein structure or to replace his multilayer ligand-protein structure with a multimeric polypeptide having peptide bonds. Nowhere is there a teaching or suggestion in Giese that such structures would “more closely mimic a natural polypeptide.” Thus, Giese provides no

motivation to modify his multilayer structure by combining or replacing it with another unrelated multimeric polypeptide having peptide bonds. Indeed, given the teachings of Giese it is difficult to envision how such a modification would be achieved.

Houghten does not provide the motivation that is missing from Giese. Houghten is in a totally different art. The multimeric structure in Houghten is being used for a totally different purpose. Nowhere is there a teaching or suggestion in Houghten that combining multimeric proteins having peptide bonds with the multilayer structure of Giese would provide a structure that "more closely mimic a natural polypeptide". Nowhere is there a teaching or suggestion in Houghten that replacing the multilayer structure of Giese with a multimeric protein having peptide bonds would provide a structure that "more closely mimic a natural polypeptide". Based on the teachings in Houghten, one of ordinary skill in the art seeking to improve the multilayer structure of Giese would not be motivated to add the polypeptide taught in Houghten to the ligand-protein multilayer structure disclosed in Giese.

Although the Patent Office has stated that combining a multimeric peptide with peptide bonds with the multilayer structure of Giese would allow one to develop a multimeric protein that "mimics the natural polypeptide with correct orientation and folding to contain desired partial biological activity", the Patent Office has not explained why or the resulting structure would more closely mimic a natural polypeptide than the structure disclosed in Giese. In addition, the Patent Office has not explained which, if any, natural polypeptide the resulting structure would mimic.

Moreover, the Patent Office has not explained what biological activity would be improved by so modifying the multilayer structure of Giese. The Giese structure is not being used as an immunogen. The Giese structure is being used to change the surface properties of an underlying substrate.

Since neither Giese nor Houghten provide any motivation to combine or to replace the multilayer structure of Giese with an unrelated multimeric protein having peptide bonds, Giese and Houghten do not render the multimeric protein of claims 42, 44, and 46 obvious.

With respect to the proposed combination of Giese and Houghten, it is not enough that one may modify a reference in view of a second reference, but rather it is required that the second reference suggest the modification of the first reference, and not merely provide the capability of modifying the first reference.

The law is quite clear that in order for a claimed invention to be rejected on obviousness, the prior art must suggest the modifications sought to be patented. In re Gordon, 221 USPQ 1125, 1127 (Fed. Cir. 1984); ACS Hospital Systems, Inc. v. Montefiore Hospital, 221 USPQ 929, 933 (Fed. Cir. 1984). The foregoing principle of law has been followed in Aqua-Aerobic Systems, Inc. v. Richards of Rockford, Inc., 1 USPQ2d 1945, 1956 (D.C. Ill. 1986). In the Aerobic case, the court stated that the fact that a prior reference can be modified to show the claimed invention does not make the modification obvious unless the prior reference suggests the desirability of the modification. The Court of Appeals for the Federal Circuit in the case of In re Gorman, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991) stated:

When it is necessary to select elements of various teachings in order to form the claimed invention, we ascertain whether there is any suggestion or motivation in the prior art to make the selection made by the applicant [citation]. 'Obviousness can not be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination.'

....

The references themselves must provide some teaching whereby the applicant's combination would have been obvious. (citations omitted)

Thus, it is clear that where an individual reference does not teach the entire invention, then the modification which the invention represents must be suggested and motivated by some other reference, which is not the case here.

Moreover, even if one were to combine the multimeric protein taught in Houghten with the multilayer structure taught in Giese, one still would not achieve the multimeric protein recited in claims 42, 44, and 46 of the instant application. Claims 42, 44, and 46 recite a multimeric protein comprising a plurality of proteins or polypeptides, or both that a) are linked to each other by peptide bonds, and b) have a binding site for a sugar, a protein, a peptide, a nucleic acid, a hormone, a vitamin, a co-factor, an anion other than a hydroxyl ion, or a cation other than a hydrogen ion. Combining the multilayer structure taught in Giese with the multimeric protein taught in Houghten would not produce such a structure. Replacing the multilayer structure in Giese with the multimeric protein taught in Houghten would not produce such a structure.

Accordingly, Giese and Houghten, even when combined, do not render the multimeric proteins of claims 42, 4,4, and 46 obvious.

In view of the above-described amendments and remarks, Applicants submit that claims c 1, 2, 6-10, 12-14, 41-47, 50, and 51-57 are respectfully are now in condition for allowance. Prompt notice of such allowance is respectfully requested.

Respectfully submitted

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